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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Ronald J. Pettis, et al.

Confirmation No.: 6991

Application No.: 10/803,735

Group Art Unit: 1646

Filed: March 17, 2004

Examiner: To be assigned

For: **METHOD FOR ALTERING DRUG
PHARMACOKINETICS BASED ON
MEDICAL DELIVERY PLATFORM**

Attorney Docket No.: 11219-036-999
(500752-999035, P-4901P1C1)

Date: July 26, 2005

**INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §1.56 AND §1.97**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 and § 1.97 to inform the Patent Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of any claim of the application, Attorneys for Applicants hereby invite the Examiner's attention to the references **A01-A37, B01-B19 and C01-C64** listed on the attached revised form PTO 1449 entitled "List of References Cited by Applicant." A copy of references **B18-B19, C01, C06, C10, C23, C35, C37-C38, C40-C41, C48, C52, and C54-C55** is submitted herewith.

This application is a continuation of U.S. application No. 09/893,746, filed June 29, 2001, which is a continuation in part of U.S. application No. 09/606,909, filed June 29, 2000. Pursuant to 37 C.F.R. § 1.98(d), copies of the listed references **B01-B17 and C02-C05, C07-C09, C11-C22, C24-C34, C36, C39, C42-C47, C49-C51, C53, C56-C64** have not been included herein as such copies are available in parent application No. 09/606,909, filed June 29, 2000. Applicants will provide copies of references **B01-B17 and C02-C05, C07-C09, C11-C22, C24-C34, C36, C39, C42-C47, C49-C51, C53, C56-C64** upon request by the Examiner.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CW/

Identification of the listed references is not meant to be construed as an admission of Applicants or Attorneys for Applicants that such references are available as "prior art" against the subject application. Consequently, Applicants respectfully decline to use form PTO-1449, since this form identifies all of the references cited therein as "Prior Art." As an alternative, Applicants submit herewith a "revised form PTO 1449" entitled "List of References Cited" instead of "List of Prior Art Cited".

Applicants respectfully request that the references be made of record in the file history of the application.

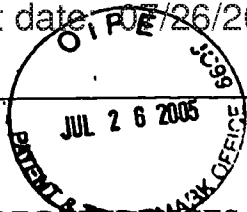
No fee is believed due. However, should the Patent and Trademark Office determine otherwise, please charge any required fee to Jones Day Deposit Account No. 50-3013. A duplicate of this sheet is enclosed for accounting purposes.

Respectfully submitted,

by: *Jacqueline Benn*
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Date: July 25, 2005

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LIST OF REFERENCES CITED BY APPLICANT
 (Use several sheets if necessary)

 ATTY DOCKET NO.
 11219-036-999
 (500752-999035, P-4901P1C1)

 APPLICATION NO.
 10/803,735

APPLICANT

Ronald J. Pettis, et al.

FILING DATE

March 27, 2004

ART UNIT

1646

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A01	2,619,962	12/02/1952	Rosenthal			
	A02	3,814,097	06/04/1974	Ganderton, et al.			
	A03	3,964,482	06/22/1976	Gerstel, et al.			
	A04	4,270,537	06/02/1981	Romaine			
	A05	4,592,753	06/03/1986	Panoz			
	A06	4,886,499	12/12/1989	Cirelli, et al.			
	A07	5,003,987	04/02/1991	Grinwald			
	A08	5,098,389	03/24/1992	Cappucci			
	A09	5,156,591	10/20/1992	Gross, et al.			
	A10	5,250,023	10/5/1993	Lee, et al.			
	A11	5,279,544	01/18/1994	Gross, et al.			
	A12	5,279,552	01/18/1994	Magnet			
	A13	5,417,662	05/23/1995	Hjertman, et al.			
	A14	5,527,288	06/18/1996	Gross, et al.			
	A15	5,582,591	12/10/1996	Cheikh			
	A16	5,591,139	01/07/1997	Lin, et al.			
	A17	5,801,057	09/01/1998	Smart, et al.			
	A18	5,820,622	10/13/1998	Gross, et al.			
	A19	5,848,990	12/15/1998	Cirelli, et al.			
	A20	5,848,991	12/15/1998	Gross, et al.			
	A21	5,876,582	03/02/1999	Frazier			
	A22	5,879,326	03/09/1999	Godshall, et al.			
	A23	5,928,207	07/27/1999	Pisano, et al.			
	A24	5,957,895	09/28/1999	Sage, et al.			
	A25	5,997,501	12/07/1999	Gross, et al.			
	A26	6,056,716	05/02/2000	D'Antonio, et al.			
	A27	6,099,504	08/08/2000	Gross, et al.			
	A28	6,200,291	03/13/2001	Di Pietro			
	A29	6,319,224	11/20/2001	Stout, et al.			
	A30	6,334,856	01/01/2002	Allen, et al.			
	A31	6,346,095	02/12/2002	Gross, et al.			
	A32	6,482,176	11/19/2002	Wich			
	A33	2003/0073609	04/17/2003	Pinkerton			
	A34	2004/0028707	02/12/2004	Pinkerton			
	A35	2004/0073160	04/15/2004	Pinkerton			
	A36	2004/0170654	09/02/2004	Pinkerton			

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CW/

	A37	2004/0175401	09/09/2004	Pinkerton			
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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	B01	WO 94/23777	10/27/1994	PCT				
	B02	WO 96/17648	06/13/1996	PCT				
	B03	EP 0 429 842	08/28/1996	EP				
	B04	WO 96/37256	11/28/1996	PCT				
	B05	WO 96/37155	11/28/1996	PCT				
	B06	WO 97/21457	06/19/1997	PCT				
	B07	WO 99/43350	09/02/1999	PCT				
	B08	WO 99/64580	12/16/1999	PCT				
	B09	WO 00/09186	02/24/2000	PCT				
	B10	CA 2 349 431	05/25/2000	Canada				
	B11	WO 00/67647	11/16/2000	PCT				
	B12	WO 00/74763	12/14/2000	PCT				
	B13	EP 1 086 718	03/28/2001	Europe				
	B14	EP 1 086 719	03/28/2001	Europe				
	B15	EP 1 088 642	04/04/2001	Europe				
	B16	EP 1 092 444	04/18/2001	Europe				
	B17	WO 02/11669	02/14/2002	PCT				
	B18	WO 02/083232 ✓	10/24/2002	PCT				
	B19	WO 03/002175 ✓	01/09/2003	PCT				

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

C01	"Flu vaccine: skin injection method effective in younger people," <i>American Health Line: Research Notes</i> (2004 Nov. 4)
C02	Agrawal et al., "Pharmacokinetics, biodistribution, and stability of oligodeoxynucleotide phosphorothioates in Mice," <i>Proc. Natl. Acad. Sci. USA</i> 88:7595-7599 (1991)
C03	Autret et al., "Comparaison des concentrations plasmatiques et de la tolérance d'une dose unique de calcitonine humaine administree," <i>Therapie</i> 46:5-8 (1991)
C04	Autret et al., "Comparison of pharmacokinetics and tolerance of calcitonine administered by intradermal or subcutaneous route," <i>Fundamental Clinical Pharmacology</i> 3(2):170-171 (1989)
C05	Bader, "Influenza vaccine experience in Seattle," <i>Am. J. Public Health</i> 70(5):545 (1980)
C06	Belshe et al., "Serum antibody responses after intradermal vaccination against influenza," <i>New England Journal of Medicine</i> 351(22):2286-2294 (2004)
C07	Benoni et al., "Distribution of Cefazidime in Ascitic Fluid, Antimicrobial Agents and Chemotherapy," 25(6):760-763 (1984)
C08	Bickers et al., editors, "Glucocorticosteroids," <i>Clinical Pharmacology of Skin Disease</i> 57-90, Churchill Livingstone, Inc. (1984)
C09	Bocci et al., "The lymphatic route. IV. pharmacokinetics of human recombinant interferon a2 and natural interferon beta administered intradermally in rabbits," <i>International Journal of Pharmaceutics</i> 32:103-110 (1986)
C10	Branswell, "Vaccine stretching may be an option for future shortages, pandemics: studies," <i>Canadian Press News Wire</i> (2004 Nov. 3)
C11	Bressolle et al., "A Weibull distribution model for intradermal administration of Cefazidime," <i>Journal of Pharmaceutical Sciences</i> 82(11):1175-1178 (1993)
C12	Bronaugh et al., "Methods for in vitro percutaneous absorption studies. II. animal models for human skin," <i>Toxicol Appl. Pharmacol.</i> 62(3):481-488 (1982)
C13	Brooks et al., "Intradermal administration of bivalent and monovalent influenza vaccines." <i>Ann. Allergy. Aug.</i> 39(2):110-112 (1977)

C14	Brown et al., "The immunizing effect of influenza A/New Jersey/76 (Hsw1N1) virus vaccine administered intradermally and intramuscularly to adults." <i>J. Infect. Dis.</i> 136 Suppl:S466-71 (1977)
C15	Burkoth et al., "Transdermal and transmucosal powdered drug delivery, critical Review™ in therapeutic drug carrier systems 16 (4):331-384 (1999)
C16	Callen, "Intralesional corticosteroids," <i>Journal of the American Academy of Dermatology, University of Louisville School of Medicine</i> 149-151 (1981)
C17	Corbo et al., "Transdermal controlled delivery of propranolol from a multilaminate adhesive device." <i>Pharm Res.</i> 6(9):753-758 (1989)
C18	Cossum et al., "Disposition of the c-labeled phosphorothioate oligonucleotide ISIS 2105 after intravenous administration to rats," <i>The Journal of Pharmacology and Experimental Therapeutics</i> 267(3):1181-1190 (1993)
C19	Cossum et al., "Pharmacokinetics of c-labeled phosphorothioate oligonucleotide, ISIS 2105 after administration to rats," <i>The Journal of Pharmacology and Experimental Therapeutics</i> 269(1):89-94 (1994)
C20	Crooke et al., "A pharmacokinetic evaluation of c-labeled afovirsen sodium in patients with genital warts," <i>Clinical Pharmacology & Therapeutics</i> 56(6):641-646 December (1994)
C21	Crowe, "Experimental comparison of intradermal and subcutaneous vaccination with influenza vaccine," <i>Am. J. Med. Technol.</i> 31(6):387-96 (1965)
C22	Firooz, et al., "Benefits and risks of intralesional corticosteroid injection in the treatment of dermatological diseases," <i>Clinical and Experimental Dermatology</i> 20(5):363-370 (1995)
C23	Fjerstad, "U. Minnesota professor uses alternative flu vaccine technique," <i>FSView & Florida Flambeau via U-Wire</i> (2004 Nov. 15)
C24	Foy et al., "Efficacy of intradermally administered A2 Hong Kong vaccine," <i>JAMA</i> 213(1):130 (1970)
C25	Glenn et al., "Advances in vaccine delivery: transcutaneous immunisation." <i>Exp. Opin. Invest. Drugs</i> 8(6):797-805 (1999)
C26	Goodarzi et al., "Organ distribution and stability of phosphorothioated oligodeoxyribonucleotides in mice," <i>Biopharmaceutics & Drug Disposition</i> 13(3):221-227 (1992)
C27	Gramzinski et al. "Immune response to a hepatitis B DNA vaccine in Aotus monkeys: a comparison of vaccine formulation, route, and method of administration," <i>Mol. Med.</i> 4(2):109-18 (1998)
C28	Halperin et al., "A comparison of the intradermal and subcutaneous routes of influenza vaccination with A/New Jersey/76 (swine flu) and A/Victoria/75: report of a study and review of the literature," <i>Am. J. Public Health.</i> 69(12):1247-1251 (1979)
C29	Haynes et al., "Ultra-long-duration local anesthesia produced by injection of lecithin-coated methoxyflurane microdroplets," <i>Anesthesiology</i> 63(5):490-499 (1985)
C30	Henry et al., "Microfabricated microneedles: a novel approach to transdermal drug delivery," <i>Journal of Pharmaceutical Sciences</i> 87(8):922-925 (1998)
C31	Herbert et al., "Comparison of responses to influenza A/New Jersey/76-A/Victoria/75 virus vaccine administered intradermally or subcutaneously to adults with chronic respiratory disease," <i>J. Infect. Dis.</i> 140(2):234-238 (1979)
C32	Jakobson et al., "Variations in the blood concentration of 1,1,2-trichloroethane by percutaneous absorption and other routes of administration in the guinea pig," <i>Acta Pharmacologica et Toxicologica</i> 41(5):497-506 (1977)
C33	Jarratt et al., "The effects of intradermal steroids on the pituitary-adrenal axis and the skin," <i>The Journal of Investigative Dermatology</i> 62(4):463-466 (1974)
C34	Kaushik et al., "Transdermal Protein Delivery Using Microfabricated Microneedles," (1 page) (1999)
C35	Kenney et al., "Dose sparing with intradermal injection of influenza vaccine," <i>New England Journal of Medicine</i> 351(22):2295-2301 (2004)
C36	Kirkpatrick et al., "Local aesthetic efficacy of methoxyflurane microdroplets in man," <i>Anesthesiology</i> 67(3A):254 (1987)
C37	Knox et al. "New research shows intradermal rather than intramuscular vaccine injection could stretch flu vaccine supplies," <i>National Public Radio: All Things Considered</i> (2004 Nov. 3)
C38	Kohn, "Flu shot technique yields more doses, studies find; critics say injecting skin rather than muscle is too difficult for common use," <i>The Baltimore Sun: Telegraph</i> 3A (2004 Nov. 4)
C39	Leroy et al., "Pharmacokinetics of ceftazidime in normal and uremic subjects," <i>Antimicrobial Agents and Chemotherapy</i> 25(5):638-642 (1984)
C40	Majeski et al., "Technique could stretch vaccine; changing the way shots are given means the current supply of flu vaccine could immunize 10 times as many people, two Minnesota physicians say" <i>Saint Paul Pioneer Press: Main 1A</i> (2004 Oct. 27)
C41	Majeski, "Alternate flu shot less effective in elderly; doctors proposed method to stretch vaccine supply," <i>Saint Paul Pioneer Press: Main 17A</i> (2004 Nov. 4)
C42	Márián et al., "Hypoglycemia activates compensatory mechanism of glucose metabolism of brain," <i>Acta Biologica Hungarica</i> 52(1):35-45 (2001)

/Catherine Witczak/ (12/13/2008)

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. NLP 1554974 /CW/

C43	McAllister, et al., "Solid and Hollow Microneedles for transdermal protein delivery," <i>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater. Controlled Release Society</i> . 26:192-193 (1999)
C44	McAllister et al., "Three-dimensional hollow microneedle and microtube arrays," <i>Solid-State Sensors and Actuators Transducers-Conference</i> ; 1098-1103 (1999)
C45	McElroy et al., "Response to intradermal vaccination with A2, Hong Kong variant, influenza vaccine." <i>N. Engl. J. Med.</i> 281(19):1076 (1969)
C46	McGugan et al., "Adrenal suppression from intradermal triamcinolone," <i>The Journal of Investigative Dermatology</i> 40:271-272 (1963)
C47	Merriam-Webster's Collegiate Dictionary, 10 th Edition, 1998, Merriam-Webster, Inc., Springfield, MA, p. 306
C48	Montagne et al., "Intradermal influenza vaccination - can less be more?" <i>New England Journal of Medicine</i> 351(22):2330-2332 (2004)
C49	Niculescu et al., "Efficacy of an adsorbed trivalent split influenza vaccine administered by intradermal route." <i>Arch. Roum. Path. Exp. Microbiol.</i> 40(1):67-70 (1981)
C50	Payler DK. "Intradermal influenza vaccine using Portojet 1976," <i>Br. Med. J.</i> 2(6095):1152 (1977)
C51	Payler et al. "Intradermal influenza vaccination," <i>Br. Med. J.</i> 2(921):727 (1974)
C52	Rindfleisch et al., "La Crosse finding could curtail flu vaccine shortages," <i>Wisconsin State Journal</i> D9 (2004 Nov. 14)
C53	Scott et al., "Toxicity of Interferon," <i>British Medical Journal</i> 282:1345-1348 (1981)
C54	Shute, "Second thoughts on the flu vaccine," <i>Science & Society; Public Health</i> 137(17):80
C55	Smith, "Low-dose vaccine helps block flu, study says younger adults seen benefiting," <i>The Boston Globe: National/Foreign A2</i> (2004 Nov. 4)
C56	Supersaxo et al., "Recombinant human interferon Alpha-2a: delivery to lymphoid tissue by selected modes of application," <i>Pharmaceutical Research</i> 5(8):472-476 (1998)
C57	Sutherest, "Treatment of pruritus vulvae by multiple intradermal injections of alcohol. a double-blind study," <i>British Journal of Obstetrics and Gynecology</i> 86:371-373 (1979)
C58	Sveinsson, "Investigation on the influence of insulin and adrenalin in rabbits with alimentary fatty liver and muscles and on the content of fat and sugar in blood," 8:66-86 (1939)
C59	Tauraso et al., "Effect of dosage and route of inoculation upon antigenicity of inactivated influenza virus vaccine (Hong Kong strain) in man," <i>Bull. World Health Organ.</i> 41(3):507-16 (1969)
C60	The American Heritage College Dictionary, 2000, 3 rd Edition; Houghton Mifflin Company, Boston, New York, p. 368
C61	The Merck Manual of Diagnosis and Therapy, 1999, 17 th Edition, Beers & Berkow, ed., Merck Research Laboratories, Division of Merck & Co., Inc., Whitehouse Station, NJ, pp. 2555-2571
C62	Ward et al., "Puritus vulvae: treatment by multiple intradermal alcohol injections," <i>British Journal of Dermatology</i> 93(2):201-204 (1975)
C63	Wu et al., "Pharmacokinetics of methoxyflurane after its intra-dermal injection as lecithin-coated microdroplets," <i>Journal of Controlled Release</i> 9:1-12 (1989)
C64	Zaynoun et al., "The effect of intracutaneous glucocorticoids on plasma cortisol levels," <i>British Journal of Dermatology</i> 88(2):151-156 (1973)

EXAMINER

/Catherine Witczak/ (12/13/2008)

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.